





Appl. No.: 10/828,630

Request for Review of Final Rejection

Appl. No.: 10/828,630

Confirmation No.: 5340

Applicants: Jill E. Parker et al.

Filed: 04/09/2004

Title: Curlicue Vaccine Strain of Bacillus Anthracis

T.C./Art Unit 1645

Examiner: Mark Navarro

Docket No.: AFD 503

Customer No.: 26902

Commissioner for Patents

PO Box 1450

Alexandria VA 22313-1450

### **Request for Review of Final Rejection of October 6, 2005**

Sir:

In response to the Final Rejection of October 6, 2005, the Assignee (Secretary of the Air Force) respectfully submits the following Request for Review.

#### **Reasons for Request**

##### **Errors in Rejection: Claim 1**

The assignee respectfully asserts that it was erroneous to reject Claim 1 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. A prima facie case of nonenablement has not been established.

A) As stated in MPEP 2164.04, "the examiner has the initial burden to establish a reasonable basis to question the enablement provided for the

claimed invention. [Citing *In re Wright*] ... (examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure)." The Final Rejection has failed to provide a reasonable explanation directed to the scope of rejected Claim 1 in this case: a "vaccine strain." The Final Rejection is improperly based on one word in Claim 1: "vaccine." This one word is improperly treated as if it were a red flag that prevents patenting.

B) As stated in MPEP 2164, "to comply with 35 U.S.C. 112, first paragraph, it is not necessary to 'enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim limitation to that effect.'" [Citing *CFMT, Inc.*] The Final Rejection's insistence on prevention is an improper insistence on enabling a perfected, commercially viable embodiment. It is improper because Claim 1 does not describe a perfected, commercially viable embodiment. Claim 1 should be read in light of the following material in the Specification for example: "a vaccine strain of *Bacillus anthracis* that will *enable identification of new genes* that contribute to the pathogenesis of the organism and thereby elucidate new antigens that play a role in eliciting a specific, protective immune response early in the infection process." Specification Paragraph [0021][emphasis added]. (See further discussion at Pages 7-8 of Amendment and Reply to Office action of April 4, 2005.)

C) As stated in MPEP 2164.04, "References should be supplied if possible to support a *prima facie* case of lack of enablement ..." In this case, the Final

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Rejection has not supplied a reference that supports a *prima facie* case of lack of enablement. The published application of Simonson, 20030143636A1, cited by the Final Rejection, is not relevant to the language of rejected Claim 1. The Simonson reference does not contain the phrase “vaccine strain” that is used in Claim 1. (See further discussion at Page 8 of Amendment and Reply to Office action of April 4, 2005.)

### **Errors in Rejection: New Claim 2**

The Final Rejection fails to state a definite ground for objecting to or rejecting this claim. There is only a hypothetical, conditional ground for an objection, “should claim 1 be found allowable,” which has not happened. “Where a claim is refused for any reason relating to the merits thereof it should be “rejected” and the ground of rejection fully and clearly stated... The examiner should designate the statutory basis for any ground of rejection by express reference to a section of 35 U.S.C...” MPEP 707.07(d). In making a final rejection, “the examiner shall repeat or state all grounds of rejection ... clearly stating the reasons ...” 37 CFR § 1.113. Claim 2 is refused for some reason relating to the merits, but the ground of rejection is not fully and clearly stated. A *prima facie* case for rejection of Claim 2 has not been established.

### **Errors in Rejection: New Claims 3-4**

It was erroneous to reject Claims 3-4, under 35 U.S.C. 102, as being anticipated by Ivins, US Pat. No. 6,387,665, and Keim, US Patent Application 20020055628A1. A *prima facie* case of anticipation has not been

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established. As stated in MPEP 2131, to anticipate a claim, a reference must teach every element of the claim. The following are some limitations in the rejected claims which are not described in the references relied upon: thermal resistance (Claims 3 and 4), and delayed onset of death in a laboratory animal (Claim 4). The Examiner's references do not mention thermal resistance or delayed onset of death. Thus a *prima facie* case of anticipation has not been established.

In conclusion, the Final Rejection omits essential elements needed to make a *prima facie* case for rejection, concerning Claims 1-4. Assignee respectfully submits that the Final Rejection should be withdrawn, and requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

  
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